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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,941	HENDERSON ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/18/03; 9/15/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action responds the Amendment received on September 28, 2004.

Preliminary Amendment

The Office acknowledges the cancellation of claims 1-20.

Claims 21-25 are pending and are under prosecution therefore.

Priority

Applicants are advised that the effective priority date of the instant application is determined as April 27, 2000 for the following reasons.

All applications filed prior to the above-recited date, to which the instant applications claim priority under 35 U.S.C. 120, fails to provide a proper description of the instantly claimed subject matter because those applications do not have description for a full-length polypeptide of SEQ ID NO: 809, but only a fragment of said polypeptide (identified as L522S, or SEQ ID NO: 786).

The polypeptide of SEQ ID NO: 786 consists of 105 residues, while the instant SEQ ID NO: 809 consists of 160 residues. Based on this finding, the applications filed prior to April 27, 2000 does not provide proper written support for the limitation, "polypeptide comprising an amino acid sequence having at least 90% identity" as the polypeptide of SEQ ID NO: 786 only has 67.5% of the SEQ ID NO: 809.

Thus, claims 21 and 23 would have an effective filing date of April 27, 2000.

With regard to claims 22, 24, and 25, which embrace embodiments that fall outside of the residues described in SEQ ID NO: 786, would also fall under the same effective filing date of April 27, 2000.

The prior art is applied based on the above-determined effective filing date.

Double Patenting

The rejection of claim 20 under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,630,574 B1, made in the Office Action mailed on June 29, 2004 is withdrawn in view of the Amendment received on September 28, 2004, canceling claim 20.

The rejection of claims 21-25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,630,574, made in the Office Action mailed on June 29, 2004 is withdrawn in view of the Terminal Disclaimer filed on October 26, 2004.

Claim Rejections - 35 USC § 112 - Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 21 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on June 29, 2004 is maintained for the reasons of record.

Applicants' arguments received on September 28, 2004 have been fully considered but they are not found persuasive.

Applicants' arguments are address in the same order they are presented.

Applicants argue that the instant specification provides adequate written description to support the genus of polypeptides with at least 90% sequence identity with SEQ ID NO: 809 because a representative number of species as well as identifying characteristics have been met (page 3, Response).

With regard to the demonstration of a representative number of species embraced by the genus, Applicants argue that such demonstration does not require the description to be of such specificity that it would provide individual support for each species the genus embraces and since a reference sequence (i.e., SEQ ID NO: 809) has been disclosed, one skilled in the art would "readily identify a claimed sequence and recognize that Applicants were in possession of said sequence at the time the application was filed.

The instant application describes a single species – SEQ ID NO: 809 – which is a polypeptide consisting of 160 residues. Any polypeptide having at least 90% homology to a protein having 160 residues would amount to an enormous number of species embraced in this genus.

For example, a polypeptide having 160 residues and 90% homology to SEQ ID NO: 809 would need to have 16 different residues. Considering that these 16 residues would appear at the N-terminus of the polypeptide (i.e., from residue 145-160), based on 20 different amino acid residues, there would be 20^{16} different possible 16 mers, resulting in 6.5×10^{20} different species of polypeptides having 90% homology to SEQ ID NO: 809, wherein all species would have different residues occurring at residue position 145-160. However, the claims embrace a polypeptide having ***at least 90%*** identity as well as allowing the different residues to be found

anywhere across the polypeptide. Therefore, the species of polypeptides embraced by this genus would be enormous.

Such genus would include polypeptides which have any function, the function of which has not been described in the specification.

As already set forth in the previous Office Action, the specification discloses SEQ ID NO: 808 which corresponds to the cDNA encoding the single species of polypeptide of SEQ ID NO: 809. The polypeptide of SEQ ID NO: 809 is disclosed contemplated as being a novel isoform of cancer testis antigen, XAGE-1 (page 165, lines 13-29), present in effusion fluid from lung cancer patients (page 186). SEQ ID NO: 809 meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims are directed to an isolated polypeptide that is at least 90% homologous to the polypeptide of SEQ ID NO: 809 (instant claim 21) as well as said polypeptide that binds an antibody specific for a polypeptide of SEQ ID NO: 809 (instant claim 23). The specification provides insufficient written description to support the genus encompassed by the claim because the claims embrace a polypeptide of at least 90% homology of ***any and all function*** to which applicants have not reasonable described. A single disclosed species of SEQ ID NO: 809 would not establish a representative number of species embraced by the genus of the claims.

Applicants argue that the instant specification discloses sufficient identifying characteristics for L552S-related polypeptides that are common to the genus of polypeptides with at least 90% identity to a polypeptide of SEQ ID NO: 809 since the reference sequence SEQ ID NO: 809 have been provided and thus a skilled artisan would understand that Applicants had possession of said polypeptide at the application was filed (page 4, Response).

What Applicants have identified is what appears to be an isomer of XAGE-1, useful as a cancer marker, wherein no further identification of function nor the regions of the protein that are critical to the function had been made.

Thus, a skilled artisan, would not readily recognize that an enormous number of species of polypeptides having 90% homology to SEQ ID NO: 809, having any function, was possessed by Applicants at the time the invention was made.

A proper demonstration of identifying characteristics is disclosed in Example 14 of the written description training material, wherein a claim drawn to a protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 ***and catalyzes the reaction of A → B*** is deemed to be described when the specification conveys to a skilled artisan that a ***functional description of the protein essential to the operation*** of the claimed invention is recited in the claim. Since the procedure for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described ***which will identify other proteins having the claimed activity***, one skilled in the art would recognize that proteins which comprise the same identity but does not have the recited function would not be embraced by such claim.

The instant situation is, however, is not analogous to the above situation because the instant specification evidences that Applicants have not yet identified what the function of the encoded polypeptide is:

"Initial database searches failed to detect any sequence homology with proteins in the database, suggesting that L552S (or polynucleotide of SEQ ID NO: 808) encodes a novel protein (the polypeptide of SEQ ID NO: 809) ***of unknown function***." (page 165, lines 13-15, specification)

Without recitation of a functional limitation, one skilled in the art would not be able to conclude that the single species of SEQ ID NO: 809 would be representative of genus of polypeptides of any function having the same degree of homology.

Therefore, with the exception of the polypeptide comprising SEQ ID NO: 809, the skilled artisan cannot envision the detailed chemical structure of the encompassed claimed polypeptide.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Also, in University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405, the court held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171,

25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

It is also noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that:

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

New Grounds of Rejection

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is determined that a reasonable number of species embraced by the claimed genus have been demonstrated.

The written description requirement ensures that, "an applicant invented the subject matter which is claimed. Further, the written description requirement for a claimed genus may be satisfied *through a* sufficient description of *a representative number of species* by 1) reduction to practice; 2) reduction to drawing; or 3) disclosure of relevant identifying characteristics (*i.e.,* structure of other physical and/or chemical properties, functional characteristics *coupled* with a known or disclosed correlation between function and structure) (MPEP 2163 at II(A)(3)(a)(ii)).

Reduction to Practice

Claim 22 is drawn to any polypeptide comprising at least 10 residues of SEQ ID NO: 809, wherein SEQ ID NO: 809 has 160 total residues. The specification discloses a single species embraced by the genus claim – SEQ ID NO: 809. The specification identifies the protein of SEQ ID NO: 809 as being full-length (page 165, lines 11-12), useful as being a marker for lung cancer (pages 165-166), but explicitly states that the function has not yet been identified.

> "Initial database searches failed to detect any sequence homology with proteins in the database, suggesting that L552S (or polynucleotide of SEQ ID NO: 808) encodes a novel protein (the polypeptide of SEQ ID NO: 809) ***of unknown function***." (page 165, lines 13-15, specification)

The total number of species that is embraced by the genus claim is unduly extensive because the claim embraces any and all proteins with at least 10 contiguous residues of SEQ ID NO: 809.

For example, the total number of species for any polypeptide that is only 100 residues in length, having at least 10 contiguous residues, would be 20^{90}, or 1.2×10^{117}. It should be noted

that this number of species only for a polypeptide that has a restriction of total of 100 residues. The claims do not limit the total size of the protein, so long as the proteins have at least 10 contiguous residues. The number of species embraced by such claim language would encompass any proteins with any functions that Applicants have not yet discovered nor disclosed.

Without a clear functional limitation to relay to a skilled artisan what Applicants had in possession at the time the application was filed, one skilled in the art would not be able to recognize that Applicants had possession of all the species embraced by the genus claim.

Reduction to Drawing

The specification disclose a reference sequence SEQ ID NO: 809 and a full-length cDNA encoding said reference sequence – SEQ ID NO: 808. No other species embraced by the claimed genus have been disclosed.

Disclosure of Relevant Identifying Characteristics

While the specification discloses some regions among SEQ ID NO: 809, which are described as being immunogenic portions (page 218), claims are not limited to those which are immunogenic, but any and all proteins with at least 10 contiguous residues to that of SEQ ID NO: 809.

The position is that Applicants have not disclosed enough number of species within the claimed genus which embraces any polypeptide comprising at least 10 contiguous residues of SEQ ID NO: 809.

As stated in *University of California v. Eli Lilly and Co.* at page 1404:

> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, ***"an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it***; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Therefore, for the foregoing reasons, the genus embraced by the claims is not sufficiently described by the number of species disclosed in the specification, and therefore, the specification lacks written description of the claims.

Claim Rejections - 35 USC § 102 – New Grounds

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 24 is rejected under 35 U.S.C. 102(a) as being anticipated by Bevan et al. (Accession No. CAB83295, publicly available as of March 2000) in light of Hoffman et al. (U.S. Patent No. 5,095,093, issued March 10, 1992).

Claim 24 is drawn to any polypeptide comprising an immunogenic portion of amino acid sequence of SEQ ID NO: 809.

The specification does not specifically limit the length of the immunogenic portion.

Bevan et al. disclose a polypeptide that has 4 residues in common with SEQ ID NO: 809, at residue position 25-28.

Hoffman et al. state that a specific antibody can be generated from as little as four amino acid residues, AGDR (Abstract, column 3, lines 26-27).

Therefore, it is determined that the polypeptide of Bevan et al. would necessarily contain an immunogenic portion, sadi immunogenic portion comprising 4 residues in common with SEQ ID NO: 809.

According to *In re Best* 195 USPQ 430, 1997, the court stated that, "Patent Office can require applicant to prove that prior art products do not necessarily or inherently posses characteristics of his claimed product wherein claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicant" (pp. 430). Absent evidence to the contrary, the polypeptide of Hoffman et al. anticipates the invention as claimed.

Conclusion

Claim 25 is objected to for being dependent on a rejected claim.

Claims 21-24 are rejected.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)

(see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
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1/7/05

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